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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/08/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/338,729

Examin r

Lauren Q Wells

Applicant(s)

GROSS, DENNIS

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-9,27-30,34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-26,31-33 and 36-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Per the interview of 4/28/03, the FINALITY of the Office Action mailed on 12/31/02, Paper No. 18, is hereby WITHDRAWN.

Claims 1-61 are pending. Claims 1-9, 27-30, 34-35 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 5/12/03, Paper No. 23, amended claims 10, 16, 37, 40-41, 44-46 and added claims 54-60.

The arguments and amendments to the claims filed 5/12/03, Paper No. 23, is sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-15, 24-26, 31, 32, 36, 37, 39-40, 43, 45, 47, 48, 49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis (5,720,949).

The instant invention is directed toward a method for the treatment of skin comprising the sequential steps of applying to the skin a composition comprising an effective amount of an acid suitable as a skin renewing acid in a cosmetically acceptable vehicle, wherein the pH of the composition is between 2.5-4, and allowing the first composition to dry on the skin; and neutralizing said first composition by applying to the skin a second composition comprising an alkaline agent and 0.1-10% of a surfactant/emulsifying agent in a cosmetically acceptable vehicle, wherein the pH is greater than about 7 to 12, and allowing the second composition to

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dry; wherein the first composition and second composition are both applied by massaging into the skin and are not thereafter removed from the skin, wherein makeup or other cosmetic is optionally applied thereafter to the skin.

Davis teaches a cosmetic mask comprising a first composition and a second composition that are applied sequentially to the face. One of the compositions comprises an acid and the other comprises an effervescent agent (abstract). The effervescent agent is preferably sodium bicarbonate and the acid is an alpha-hydroxy acid such as lactic acid (col. 2, lines 35-38). The acid component makes up about 1-30% of the second composition (col. 3, lines 61-67). Lactic acid has an inherent molecular weight of about 90. The compositions may be applied using a spatula or any other convenient applicator (col. 2, lines 42-47).

The effervescent composition may comprise from about 1-20% of a surfactant system (col. 3, lines 31-33). Surfactants such as cetareths, ceteths, laneths, nonoxynols, octoxynols, glyceryl stearate, PEG-castor oil, poloxamers, poloxamines, and steareths are taught at column 5, line 47-col. 6, line 35. Davis teaches ethoxylated sorbitan esters with fatty acids or alcohols and ethoxylated esters having preferably 14-18 carbon atoms, which encompass polysorbate 20 (col. 5, line 60-col. 6, line 4).

The pH of the effervescent composition is from about 7.5 to about 9, preferably between 7.8 and 8.3 (col. 7, lines 58-60). The pH of the acid composition is from about 3.5 to about 6 (col. 8, lines 50-64). As a further note, pH is an inherent property of an acid or alkaline agent. Therefore, the pH of a composition comprising an acid or an alkaline agent is inherently either acidic or basic, respectively, unless specifically altered.

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For additional suitable acids, see col. 9, lines 8-13. See Example 1 at col. 12 for one composition comprising 5wt.% sodium bicarbonate, 1.5% glyceryl stearate, 5% cetyl alcohol, 1.5% PEG-100 stearate and 1.5% PEG-40 castor oil with a pH of 8.0 and another composition comprising 9.1% lactic acid with a pH of 4.9. The reference teaches at column 13, lines 7-9, that the composition bubbles because of the reaction between the effervescent agent and the acid. This is interpreted as meaning that the alkaline, effervescent agent neutralizes the acid component.

Davis teaches the compositions as being massaged into the skin. At col. 10, lines 58-60, it is disclosed that the cream mask composition is allowed to remain on the face for up to about 10 minutes. At col. 11, line 66-col. 12, line 2, it is disclosed that the composition is left on the skin for up to about 30 minutes after which time the composition can be scraped from the skin. Thus, the compositions are given time to dry once they are applied to the skin.

The reference does not teach applying the neutralizing composition to the acid composition. However, it is respectfully pointed out that no criticality is seen in the particular order of application. Since the compositions are used in conjunction with one another, the ultimate effect to the skin is the same. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the alkaline solution to the acid solution because of the expectation of achieving similar cosmetic effects.

Regarding the limitation "and are not thereafter removed from the skin" in the instant independent claims, it is respectfully pointed out that giving the broadest interpretation of this language, Davis meets this limitation. The Examiner respectfully points out that Davis teaches that his compositions are allowed to remain on the face for up to about 30 minutes. Thus, the

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compositions are not removed from the skin for at least 30 minutes. Since the instant specification does not define the time period referred to by this phrase and since all cosmetic compositions must ultimately be removed from the skin, the teachings of Davis meet this limitation.

The prior art and the instant invention teach the same method of applying the same composition. Regarding the property limitations in the instant claims, it is respectfully pointed out that the composition of the prior art containing the same components as instantly claimed must exhibit the same properties, as a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

It is respectfully pointed out that for the purposes of searching for an applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Claims 16-21, ~~46~~ 51, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis as applied to claims 10-15, 24-26, 31, 32, 36, 37, 39-40, 43, 45, 47, 48, 49, 50 above, and further in view of Kunz et al. (6,171,347).

Davis is applied as discussed above. The reference lacks kits.

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Kunz et al. teach a multi-compartment kit comprising a first and second composition with a pH of 1,8-6, which overlaps the instantly claimed pH ranges of the acidic composition. The second composition comprises an acid such as alpha-hydroxycarboxylic acids. See claim 18. See Examples 1.1-1.5 bridging cols. 11-12 for a composition comprising sodium hydroxide, sodium lauryl ether sulfate and ammonia, and stripper gel compositions comprising ascorbic acid, inter alia. An applicator is taught at col. 11, lines 64-65. The pH value of the first composition is preferably from 5-9 (col. 9, lines 7-8). This either overlaps or encompasses the instantly claimed pH ranges of the alkaline composition. At col. 9, lines 14-16 it is taught that buffers such as alkali carbonates can be added to the composition. For surfactant/emulsifiers, see col. 8, lines 52-57.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of Davis in the kit of Kunz et al. because of the expectation of achieving ease of application by providing a single carrier for two compositions that must be sequentially applied.

Claims 33, 38, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis as applied to claims 10-15, 24-26, 31, 32, 36, 37, 39-40, 43, 45, 47, 48, 49, 50 above, and further in view of Smith et al (5,242,433).

Davis is applied as discussed above. The reference lacks pads.

Smith et al. teach a packaging system of applicator pads for topical drug delivery and a method of applying two dermatological agents to the skin sequentially using the applicator pads (title and abstract).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of Davis as being applied by a pad, as taught by Smith et al., because Davis teaches that the compositions can be applied to the skin via a spatula or other means and because of the expectation of achieving an applicator that is flexible and conforms to the contours of the face, allowing for easier application of the compositions.

Claims 41-42, 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Kunz et al. as applied to claims 10-21, 24-26, 31, 32, 36, 37, 39-40, 43, 45-51 and 53 above, and further in view of Smith et al. (5,242,433).

Davis and Kunz et al. are applied as discussed above. The references lack pads.

Smith et al. teach a packaging system of applicator pads for topical drug delivery and a method of applying two dermatological agents to the skin sequentially using the applicator pads (title and abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of Davis as being applied by a pad, as taught by Smith et al., because the combined references teach that the compositions can be applied to the skin via a spatula or other means and because of the expectation of achieving an applicator that is flexible and conforms to the contours of the face, allowing for easier application of the compositions.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Kunz et al. as applied to claims 10-21, 24-26, 31, 32, 36, 37, 39-40, 43, 45-51 and 53 above, and further in view of Linn et al. (4,797,273) and STN Registry Print-out.

Davis and Kunz et al. are applied as discussed above. The references lack octoxynol-9 and polysorbate 20.

Linn et al. teach skin moisturizing microemulsions. Sorbates, such as polysorbate 21 and octoxynol-9 are taught as cosmetically acceptable surfactants. See Col. 6, lines 14-33.

As taught by the REGISTRY file printout for polysorbate-20 obtained on STN, polysorbate-20 and polysorbate-21 are considered equivalent compounds.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach polysorbate-20 and/or octoxynol-9 as the surfactant(s) in the alkaline composition of the combined references because of the expectation of achieving similar surfactant effects with surfactants that are cosmetically acceptable. Furthermore, it is respectfully pointed out that Davis teaches polysorbates and octoxynol as surfactants, and it is within the skill in the art to substitute one known species of surfactant for another.

Claims 54, 56, 57, 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis as applied to claims 10-15, 24-26, 31, 32, 36, 37, 39-40, 43, 45, 47, 48, 49, 50 above, and further in view of Hahn et al. (2002/0098210).

Davis is applied as discussed above. Davis teaches the alkaline composition in the form of a cream and the acid composition in the form of a gel. The reference lacks liquid forms of the compositions.

Hahn et al. teach cosmetic compositions for application to the skin. Liquid, gel and creams are taught as interchangeable cosmetic formulations. See title, abstract; Claims 1 and 45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of Davis in the form of a liquid because Hahn et al. teach liquid, gel and creams as interchangeable cosmetic composition forms.

Claims 55 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Kunz et al. as applied to claims 10-21, 24-26, 31, 32, 36, 37, 39-40, 43, 45-51 and 53 above, and further in view of Hahn et al. (2002/0098210).

Davis and Kunz et al. are applied as discussed above. Davis teaches the alkaline composition in the form of a cream and the acid composition in the form of a gel. The references lack liquid forms of the compositions.

Hahn et al. teach cosmetic compositions for application to the skin. Liquid, gel and creams are taught as interchangeable cosmetic formulations. See title, abstract; Claims 1 and 45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of the combined references in the form of a liquid because Hahn et al. teach liquid, gel and creams as interchangeable cosmetic composition forms.

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Smith et al. as applied to claims 10-15, 24-26, 31, 32, 33, 36, 37-40, 43-45, 47, 48, 49, 50 above, and further in view of Hahn et al.

Davis and Smith et al. are applied as discussed above. Davis teaches the alkaline composition in the form of a cream and the acid composition in the form of a gel. The references lack liquid forms of the compositions.

Hahn et al. teach cosmetic compositions for application to the skin. Liquid, gel and creams are taught as interchangeable cosmetic formulations. See title, abstract; Claims 1 and 45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of the combined references in the form of a liquid because Hahn et al. teach liquid, gel and creams as interchangeable cosmetic composition forms.

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Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis in view of Kunz et al. in further view of Smith et al. as applied to claims 10-21, 24-26, 31, 32, 36, 37, 39-43, 45-52 and 53 above, and further in view of Hahn et al.

Davis, Kunz et al., Smith et al. are applied as discussed above. Davis teaches the alkaline composition in the form of a cream and the acid composition in the form of a gel. The references lack liquid forms of the compositions.

Hahn et al. teach cosmetic compositions for application to the skin. Liquid, gel and creams are taught as interchangeable cosmetic formulations. See title, abstract; Claims 1 and 45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the compositions of the combined references in the form of a liquid because Hahn et al. teach liquid, gel and creams as interchangeable cosmetic composition forms.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

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lqw

July 2, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

7/2/03